REMARKS

Claims 20-37 are pending, with Claim 20 withdrawn from consideration. By this Amendment, the Specification and Claim 21 are amended. No new matter is added. Consideration in view of the above amendments and following remarks is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned, "Version With Markings to Show Changes Made."

CLAIM REJECTIONS

Claims 21-36 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. The Examiner alleges that "undersinter" is indefinite as it does not appear to be a term of the art and the Specification does not appear to define what is meant by undersintering. This rejection is respectfully traversed for at least the reasons set forth below.

Applicants respectfully submit that "sintering" and "firing" are alternative words that describe the process of heating, after drying, to increase the rigidity and strength of a formed article. Sintering is a known technique, as indicated at page 491 of The Science and Engineering of Materials, second edition, 1989, ISBN 041234260X, and as shown in Modern Ceramic Engineering, second edition, by Richerson, ISBN 0-8427-8634-3, published in 1992, pages 519 to 523 and 544 to 549. For example, page 520 shows that sintering takes place in initial, intermediate and final stages. The term "undersintered" means incompletely sintered.

The term is also used in patent literature. For example, in U.S. Patent No. 3,734,767, column 4, lines 38 to 40 and column 5, lines 24 to 30. The term is also used in U.S. Patent No. 3,789,096, column 6, lines 1 to 5 and Table 1. While these patents obviously deal with ceramics, they do not disclose or foreshadow using the ceramic article to retain living cells.

In addition, U.S. Patent No. 4,626,392, to Kondo, uses the term "semisintered" and relates to a body suitable for surgical implantation. In this disclosure, the surgical implant is a dense ceramic bone replacement with a bio-compatible coating. To insure the bio-compatible coating has a strong adhesion to the substrate, the inventor has developed an anchoring method by infiltrating some bio-compatible material into the substrate.

The anchoring method involves three steps. First, the substrate that is the main load bearing bone replacement is only semisintered at about 200° to 400°C below its full densification sintering temperature to retain some of its porosity (*e.g.*, 10-40% volume). At this stage, the substrate is not mechanically strong. Second, bio-compatible materials or a mixture of bio-compatible materials and substrate materials are infiltrated into the surface of the semisintered substrate. The substrate is subsequently dried and fired to full densification temperature. The substrate now has obtained its full strength and has bio-compatible anchors finely dispersed on the surface. Third, the substrate is then coated with bio-compatible materials and fired up to a temperature of 135°C, the maximum temperature at which the coating retains its bio-compatibility. Because of the presence of the anchors, the coating adhesion is good.

In Kondo, the substrate is made of an inert material, and the only function it plays is load bearing. It does not have any bio-interactions with the surrounding tissues, except contamination. The bio-compatible coating is not porous because it is uniformly coated onto the substrate with fine powders or solutions and fired to maximum temperatures. Any porosity is very low and the pore size small (*e.g.*, sub-micron). It is impossible for the soft tissues, blood vessels and bone cells to grow into the coating or the substrate simply because there are not any suitable sized pores. The implant is a foreign object for all its lifetime. That is, it will never be absorbed or transferred into part of the human body and therefore is always inert.

In the instant invention, the implant is a porous ceramic foam made entirely of bio-compatible materials. It is intended to be used as bone graft materials of high acceptability. The foaming process makes it possible to control the pore sizes of the foam and it may be tailored into suitable combinations (*e.g.*, pore sizes between 15 and 50 micrometers encourage fibrovascular ingrowth, pore sizes of 50-150 micrometers result in aesthete formation, and pore sizes greater than 150 micrometers facilitate the ingrowth of mineralized bone). See page 8, lines 4-8. See also page 10, last line to page 11, line 3, which indicates that the pores may be infield with certain drugs such as antibiotics or growth factors, to act as a slow release agent at the site of an implant and it appears to encourage the easy attachment of in-growing bone cells compared to a dense micro structure.

A person having ordinary skill in the art upon reviewing Kondo would not undersinter ceramic bodies for the purpose of this invention because Kondo wants to semi-sinter the

substrate to provide pores for placing anchors. The bio-compatible coating has strong adhesion to the substrate. The semi-sintered substrate must be subsequently fully sintered to gain mechanical strength. So under-sintering the substrate in Kondo to be the final product is not acceptable. Undersintering the coating will not give any added benefit. The bio-compatible coating is applied to the substrate to stop the surrounding tissue rejecting the implant. There will be negligible bone cell ingrowth on the surface whether the coating is fully sintered or not. Undersintering the coating will reduce its mechanical strength and hence the chances of separation increase.

US Patent No. 6,296,826, to Fujinold, also discusses semi-sintering, but in a different context.

Accordingly, a person having ordinary skill in the art would have no difficulty in understanding the term "undersinter" and would need no further guidance. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 21-29 and 31-33 were previously rejected under 35 U.S.C. §102(b) over Sambrook et al. (WO 93/04013). In addition, Claims 21-36 were previously rejected under 35 U.S.C. §103(a) as being unpatentable over Sambrook et al. In other words, the Examiner has asserted that Sambrook discloses or teaches Claims 21-36. However, Sambrook does not disclose or teach at least the step of controlling the period between the formation of the foam and the onset of polymerization, and undersintering, as recited in amended Claim 21.

Sambrook does teach the principle of making a porous ceramic article using a polymerizable monomer. It points out at page 11, lines 5 to 9, the pores can be controlled to be remarkably uniform.

Examples VIII onwards are relevant to the claims in the instant patent application. Example VIII does not teach the steps recited in Claim 21. Example IX shares the use of a polymerizable monomer system, but there is no control of the onset of polymerization. Example IX of Sambrook teaches that the foam was left for 24 hours at room temperature. When this is done, the solids tend to settle, which affects the interior structure of the finally formed article. The same is true of Example X where the homogenized mix was left to stand for 14 hours. As a result, the product of the examples of Sambrook does not have the required properties for bone cell growth.

In contrast, in the present invention the surfactant is added and then air is introduced to form a foam. Once the foam density was achieved, the initiator and catalyst are injected to start the polymerization. In Example I of the instant application, the period between the achievement of foam density was 1.5 minutes; once the polymerization was finished, the foam was removed, and dried; then machined. The binder was burned off from the shaped article. It was then heated to a temperature below that at which the article will fully density because otherwise bone cells will not grow in the pores.

Claim 21, as amended differs from Sambrook at least because Sambrook does not teach a step to control the onset of polymerization and Sambrook does not teach a disclosure of the

undersinter to achieve the specified pore walls and struts. Accordingly, Sambrook does not disclose or teach the subject matter recited in Claim 21. Withdrawal of rejection of Claims 21-36 over Sambrook is respectfully requested.

Claims 34 and 35 were previously rejected under 35 U.S.C. §103(a) as being unpatentable over Sambrook in view of Takagi et al. (U.S. Patent No. 4,654,314). The Examiner relies upon Takagi for teaching that artificial parts comprising growth of burn cells in ceramic products is known. The Examiner also relies upon Takagi for teaching that the pores of the ceramic product should be between 1 and 600 micrometers to promote induction of new-born bone and turnover of a bone while keeping a good compatibility with a living body.

Takagi teaches the formation of a porous ceramic structure using an organic binder. It is clear that Takagi cannot use the binder alone to form pores leading to the exterior; this is why a second organic material, in particular long fibres, such as hair, are added to create the paths. The article is also fully sintered. That is, there is no disclosure or foreshadowing of the undersinter step. Accordingly, Takagi does not teach the above-discussed features of Claim 21 missing in Sambrook.

Therefore, Claim 21 is believed to be allowable over the cited prior art. Claims 20 and 22-37 depend from independent Claim 21, and are also believed to be allowable over the cited prior art.

CONCLUSION

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable consideration and allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below to further expedite prosecution of the application.

Please charge or credit our Account No. 03-0075 as necessary to affect entry and/or ensure consideration of this admission

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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March 25, 2002

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Attachments:
Version with Markings to Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Beginning at line 1, of page 1, the following paragraph has been amended as follows:

-- The invention relates to reduction of articles of [controlled] predetermined porosity.--

Beginning at page 3, line 1, the following paragraph has been rewritten:

-- It is one object of the invention to provide a method of making a porous article having [controlled] predetermined levels of porosity, interconnectivity, pore size, and mechanical properties suitable for use in various applications. --

The last paragraph of page 5, beginning at line 15, has been replaced with the following rewritten paragraph:

-- Another factor which influences the growth of the foam structure is the period before the onset of polymerization. This period can be controlled by the addition levels of the initiator and catalyst. By controlling these levels as well as the oxygen concentration within the foaming gas the length of time before polymerization starts can be controlled between an instantaneous polymerization and one which starts after a period, which can be up to 20 minutes or more. Our evaluations suggest that this period has a major influence on [cell] foam structure where the porous article is to be used as a bone substitute. --

IN THE CLAIMS:

Claim 21 is amended as follows:

21. (Amended) A method of making a porous article composed of bonded particles and having a [controlled] predetermined level of porosity, pore size and interconnectivity, the method comprising the steps of:

a) forming a dispersion comprising a liquid carrier, particles to be bonded and a polymerizable monomeric material;

b) adding a surfactant and then introducing small bubbles of oxygen containing gas into the dispersion with agitation to form a foam which is allowed or caused to coalesce;

[c) controlling an onset of polymerization; then]

[d]c) polymerizing the foamed structure;

112(2) doesn't say that rates are w/respect to predetermined

d) adjusting the period from the formation of the foam to the start of the polymerization by adding initiator and catalyst therefor at rates selected to influence the structure of the pores to be present in the porous article[,];

e) drying the structure to remove the liquid carrier and provide a solid article having pores derived from the bubbles[,]; and

f) firing the article to a temperature to remove the organic material and to undersinter the formed article and thereby form the porous article which has a porosity of 20% to 95% and comprises pore walls and struts defining pores of pore sizes [having a] in the range of 15 to 150 micrometers and in which bone cells may easily be attached.